Existing Schedule M vs Revised Schedule M

Key Aspects	Existing schedule M	Revised schedule M
Pharmaceutical Quality System (PQS)	No section in existing Schedule M or nor mentioned in sub chapters of quality system.	Newly added. Separate specific requirements mentioned.
Quality Risk Management	No section in existing Schedule M or nor mentioned in sub chapters of quality system.	Newly added. Separate specific requirements mentioned.
Product Quality Review	No section in existing Schedule M or nor mentioned in sub chapters of quality system.	Newly added. Separate specific requirements mentioned.
Good manufacturing practices (GMP) for pharmaceutical products	No section in existing Schedule M. Requirements regarding production area are mentioned nut not practices.	Newly added. Separate specific requirements mentioned.
Qualification and Validation	Product process validation requirements are specified with minimum emphasis.	Newly Added. Detailed requirements of equipment qualification along with process validation are specified.
Complaints	No separate section in existing Schedule M regarding complaints management.	Newly Added. Detailed requirements of complaint management are specified.
Product specific manufacturing requirements	In existing Schedule M, six product specific manufacture requirements are specified.	In revised Schedule M, another 5 categories are added. Total 11 product specific manufacture requirements are specified.

Existing Schedule M vs Revised Schedule M

Key Aspects	Existing schedule M	Revised schedule M
Change Control	No separate section in existing Schedule M regarding change control management.	Newly Added. Detailed requirements of change control management are specified.
Production under loan license or contract and contract analysis and other activities	No section or requirements specified in existing Schedule M.	Newly Added. Detailed requirements of contract arrangement, roles and responsibility of product quality are specified.
Self-inspection, quality audits and suppliers' audits and approval	In existing Schedule M, the activity is limited upto internal inspection.	In revised Schedule M, this activity is more clarified and extended beyond self-inspection towards supplier approval through quality audits of his premises and processes.
Documentation	In existing Schedule M, general principles of good documentation practices and electronic documents are mentioned.	In revised Schedule M, specific requirements are mentioned as per ALCOA principles from global standards. ALCOA: - Attributable, Legible, Contemporaneous, Original and Accurate.
Good manufacturing practices (GMP) for Production	In existing Schedule M, limited aspects are covered.	Newly added as separate principle with specific requirements.
Good manufacturing practices (GMP) for Quality Control	In existing Schedule M, limited aspects are covered.	Newly added as separate principle with specific requirements.
Computerized Systems	In existing Schedule M, limited aspects are covered.	Newly added as separate principle with specific requirements complying global standards.